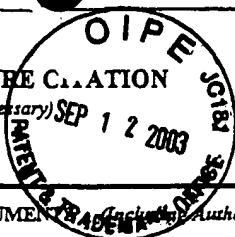


AMENDED
INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)



Docket Number (Optional)

LIC-10002/0

Application Number

09/198,798

Applicant(s)

Edward M. Lichten

Filing Date

November 24, 1998

Group Art Unit

1614

*EXAMINER INITIAL	OTHER DOCUMENTS (Indicate Author, Title, Date, Pertinent Pages, Etc.)
*	BANTING and BEST (1992) The internal secretion of the pancreas. J. Lab. Clin. Med., 7:251-266.
	BARBIROLI et al. (1995) Lipoic (thioctic) acid increases brain energy availability and skeletal muscle performance as shown by in vivo 31 P-MRS in a patient with mitochondrial cytopathy. J of Neurology, 242:472-7.
	BARRETT-CONNOR and GOODMAN-GRUEN (1995) Prospective study of endogenous sex hormones and fatal cardiovascular disease in postmenopausal women. Br. J. Med., 311:1193-6.
*	BERGE et al. (1977) Pharmaceutical salts. J. Pharm. Sci., 66:1-19.
	BERGLUND et al. (1996) Hormonal regulation of serum lipoprotein (a) levels: effects of parenteral administration of estrogen or testosterone in males. J.-Clin. Endo. Metab., 81(7):2633-7.
	BHASIN et al. (1996) The effects of supraphysiologic doses of testosterone on muscle size and strength in normal men. N. Engl. J. Med., 335(1):1-7.
	BIRKELAND et al. (1993) Level of sex hormone binding globulin is positively correlated with insulin sensitivity in men with type II diabetes. J. Clin Endo. Metab., 76(2):275-8.
	BLACK (1996) The coronary artery disease paradox: the role of hyperinsulinemia and insulin resistance and implications for therapy. Am. J. Hypertension, (Apr):9(4TPT3); 2S-10S.
	CARRUTHERS (1996) in Male Menopause., index and elect pages only. pp. 88-89 Harper Collins, London England.
	CAULEY et al. (1990) The relationship of endogenous sex steroid hormone concentrations to serum lipid and lipoprotein levels in postmenopausal women. Am. J. of Epidem, 132:884-893.
	DEFRONZO and FERRANNINI (1991) Insulin resistance. Diabetes Care, 14(3):173-194.
	FAIX et al. (1993) Quantification of menstrual and diurnal periodicities in rates of cholesterol and fat synthesis in humans. J. of Lipid Research 34:2067-2075.

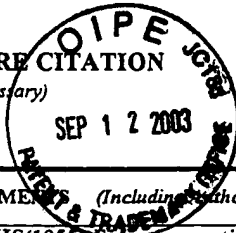
EXAMINER

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**AMENDED
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*EXAMINER
INITIAL

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

FRANKE and FUCHS(1955) Ein neues antidiabetisches Prinzip, Ergebnisse klinischer Untersuchungen.

Dt. Med. Wschr., 90:1449-1452.

[n/a - will send if able to locate]

GRIMDITCH et al. (1988) Peripheral insulin sensitivity as modified by diet and exercise training.

American Journal of Clinical Nutrition, 48:38-43.

GRODIN et al. (1973) Source of estrogen production in postmenopausal women.

J. Clin. Endocrinol. Metab., 36:207-214.

HAFFNER et al. (1993) Decreased sex hormone binding globulin predicts non-insulin dependent diabetes mellitus in women but not in men. J. Clin. Endocrin. Metab., 77:56-60.

Am. J. Epidemiology, 142:925-34.

HAFFNER et al. (1992) Relationship of sex hormone binding globulin to lipid, lipoprotein, glucose, and insulin concentrations in postmenopausal women.

Metabolism, 41:278-84.

HAUNER et al. (1994) Body fat distribution and its association with metabolic and hormonal risk factors in women with angiographically assessed coronary artery disease. Evidence for the presence of a metabolic syndrome.

Atherosclerosis, 105:209-216.

* HIGUCHI and STELLA (1987) Pro-drugs as novel delivery systems. Vol 14. of the A.C.S. Symposium Series. (Table of Contents and pp. 52-55)

* HORTON and TAIL (1966) Androstenedione production and interconversion rates measured in peripheral blood and studies on the possible site of its conversion to testosterone.

J. Clin. Invest., 45:301-313.

JANBON et al. (1942) Accidents hypglyemiques graves par un sulfamidothiadiazol (le VJ 57 ou 2254 RP).

Montpell. Med., 21-22:441-444.

[n/a - will send if able to locate]

KAPLAN (1989) The deadly quartet. Upper body obesity, glucose intolerance, hypertriglyceridemia, and hypertension.

Arch. Intern Med., 149:1514-20.

* KATSOYANNIS (1966) The chemical synthesis of human and sheep insulin.

Am. J. Med., 40:652-661.

* LEVINE (1949) The action of insulin on the distribution of galactose in eviscerated nephrectomized dogs.

J. Bio. Chem., 179:985-986.

EXAMINER

DATE CONSIDERED

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Applicant(s) Edward M. Lichten		Filing Date November 24, 1998	
Group Art Unit 1614			

*EXAMINER INITIAL	OTHER DOCUMENTS	(Including Author, Title, Date, Pertinent Pages, Etc.)
		LINDSTEDT et al. (1990) Low sex hormone binding globulin concentration as independent risk factor of development of NIDDM: 12 year follow-up of population study of women in Gothenburg, Sweden. Diabetes, 40:123-8.
	★	LOUBATIERES (1957) The hypoglycemic sulfonamides; history and development of the problem from 1942-1955. Ann. NY Acad. Sci., 71:4.
		MAURIELLO et al. (1997) Testosterone-a pharmacological adjunct in the treatment of leg ulcers. Journal of Advancement in Medicine, Vol. 10, No. 2, pp. 129-137.
		MITCHELL et al. (1994) Evidence for an association between dehydroepiandrosterone sulfate and nonfatal, premature myocardial infarction in males. Circulation, 89:89-93.
		MOLLER and EINFELDT (1984) Testosterone treatment of cardiovascular diseases. select pages only. Springer-Verlag, Berlin, Germany.
	★	MURRAY (1996) in Encyclopedia of nutritional supplements. Rockin, CA, Pima Publishing. Diabetes Mellitus, pp. 401-430
	★	MURRAY (1991) in Encyclopedia of Natural Medicine, Rockin, CA; Pima Publishing. select pages only
		NAFZIGER et al. (1991) Dehydroepiandrosterone and dehydroepiandrosterone sulfate: their relation to cardiovascular disease. Epidemiologic Reviews, Vol 12, pp. 267-293.
		NESTLER et al. (1991) A direct effect of hyperinsulinemia on serum sex hormone binding globulin levels in obese women with the polycystic ovary syndrome. J. Clinical Endocrinology & Metabolism, (1):83-9.
		NEWCOMER et al. (1994) Dehydroepiandrosterone sulfate and the risk of myocardial infarction in US male physicians: a prospective study. Am. J. of Epidemiology, 140:870-5.
		PASQUALI et al. (1995) Insulin regulates testosterone and sex hormone binding globulin concentrations in adult normal weight and obese men. J. Clinical Endocrinol. Metabol., 80(2):654-8.
		PHILLIPS et al. (1994) The Association of hypotestosteronemia with coronary artery disease in men. Arteriosclerosis & Thrombosis, 14(5):701-706.

EXAMINER	DATE CONSIDERED
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AMENDED INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		Docket Number (Optional) LIC-10002/03	Application Number 09/198,798
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Group Art Unit 1614			

*EXAMINER INITIAL	OTHER DOCUMENTS <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>
	PHILLIPS et al. (1977) Relationship between serum sex hormones and glucose, insulin, and lipid abnormalities in men with myocardial infarction. Proc. Natl. Acad. Sci., USA, 74:(4):1729-33.
	PHYSICIAN DESK REFERENCE (1988). R. Arky, consultant. Medical Economics Co., Montvale, NJ. select pages only.
	REAVEN (1988) Role of insulin resistance in human disease. Diabetes, 37:1595-1606.
*	SANGER (1960) Chemistry of insulin. Br. Med. Bull, 16:183-188.
	SOLER et al. (1989) Associations of abdominal adiposity, fasting insulin, sex hormone binding globulin, and estrone with lipids and lipoproteins in post-menopausal women. Atherosclerosis, 79:21-7. [n/a - will send if able to locate]
	TRAVIS and SAYERS (1970) in The pharmacological basis of therapeutics, Chapter 71, Insulin and oral hypoglycemic drugs, 1581-1603, Louis S. Goodman and Alfred Gilman eds., 4th ed.
*	UNGAR et al. (1957) Pharmacological studies of a new oral hypoglycemic drug. Proc. Soc. Exp. Biol. Med., 95:190-192.
	WATANABE (1918) Studies in the metabolic changes induced by administration of guanidine bases. J. Blood Chem., 33:253-265. [n/a - will send if able to locate]
	ZEGINIADOU et al. (1997) Nonlinear binding of sex steroids to albumin and SHBG. Eur Drug Metab Pharmacokinet, 22(3):229-35. [n/a - will send if able to locate]
	LARSSON and AHREN (1996) Androgen Activity as a Risk Factor for Impaired Glucose Tolerance in Postmenopausal Women. Diabetes Care, Vol. 19, No. 12, pp. 1399-1403.
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